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a distal tip which has an opening in fluid communication with the first lumen in the elongated shaft and which is oriented at an angle with respect to the longitudinal axis of the shaft and

Q3
b. a guide means which is slidably disposed within the first lumen of the tubular support means, which is configured for longitudinal movement through the first lumen and out the distal discharge opening and which has a distal extremity configured for entry into a [patient's] coronary sinus ostium and a delivery therein of a therapeutic or diagnostic device; and

c. a stabilizing means for maintaining the alignment of the tubular support means within the right atrium.

REMARKS

The first non-final Office Action mailed July 15, 2002 has been received and carefully reviewed. Claims 1-19 are pending in the application.

In paragraph 1 on page 2 of the Office Action, claims 1-16 and 18-19 were rejected under 35 U.S.C. § 112, second paragraph, as having insufficient antecedent basis for various elements.

The Applicant contends that the minor informalities identified by the Office Action do not render claims 1-16 and 18-19 indefinite as asserted by the Examiner. Applicant respectfully submits that one skilled in the art would understand the Applicant's claimed subject matter despite the minor antecedent basis informalities.

However, in the interest of expediting prosecution, claims 1, 4, 14, and 17-19 have been amended to correct the minor antecedent basis informalities identified in the Office Action. Claims 15 and 16 have been amended to correct informalities in the preambles of claims 15 and 16. The amendments presented herein are not made for purposes of patentability, nor do the amendments have a narrowing effect on the amended claims. Rather, the instant amendments were made to correct minor informalities. Therefore, it is respectfully submitted that the Applicant has not limited, nor has the Applicant intended to limit, the breadth of the claims by way of correcting minor informalities.

In paragraph 2 on page 3 of the Office Action, claims 1-5 and 17-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4033331 to *Guss et al.*

Guss et al. discloses a cardiac catheter for simplifying dye insertion procedures. The cardiac catheter has a deformable distal end that is preformed with a set curvature. The catheter is formed with two lumens: a main lumen and a wire lumen extending throughout its length. Upon insertion, a contour wire resides in the wire lumen causing the catheter to have varying degrees of curvature depending on the procedure being performed. (*Guss et al.*, col. 2, lines 8-37)

The Applicant's claimed subject matter involves a coronary sinus accessing system comprising a tubular support member, a guide member, and a stabilizing member. The guide member is configured for longitudinal movement through the first lumen and out the distal discharge opening. The guide member has a distal extremity configured for entry into a patient's coronary sinus ostium. The stabilizing member maintains the alignment of the tubular support member within the patient's right atrium.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Guss et al. fails to disclose, either expressly or inherently, several elements of Applicants independent and dependent claims. (For example, with respect to claims 1, and 17-19, *Guss et al.* fails to disclose a stabilizing member.) The Examiner points to element 22 of *Guss et al.* as a stabilizing member. However, element 22, as shown in Figure 5 of *Guss et al.* is not a stabilizing member, but is the main lumen of the catheter. Further, element 22 is described as "a main lumen" at col. 3 line 46 in *Guss et al.*

Additionally, *Guss et al.* fails to disclose a guide member which is configured for longitudinal movement through the first lumen and out the distal discharge opening and which has a distal extremity configured for entry into a patient's coronary sinus opening.

Although the Examiner points to element 26 of *Guss et al.* as a guide member, Figures 2-4 and col. 3 line 56 of *Guss et al.* illustrate and describe element 26 as a bend and not a guide member. Furthermore, the contour wire described in *Guss et al.* is used internally within the catheter to shape the catheter. There is no teaching or suggestion in *Guss et al.* that the contour wire is configured for movement out of the distal discharge opening for entry into a patient's coronary sinus opening.

Guss et al. clearly fails to teach the stabilizing member or the guide member of Applicant's claimed subject matter, either expressly or inherently. As such, claims 1 and 17-19 are not anticipated by *Guss et al.* (1)

In paragraph 3 on page 3 of the Office Action, claims 1-5 and 7-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6332881 to *Carner et al.*

Carner et al. discloses a surgical ablation tool used during open heart or open chest surgery for creating lesions or lines of ablation in tissue. The surgical ablation tool includes an electrode region that is deflectable. (*Carner et al.*, col. 3, lines 37-45)

Carner et al. fails to disclose, either expressly or inherently, several elements of Applicants independent and dependent claims. For example, with respect to claims 1 and 14, *Carner et al.* fails to disclose a distal tip which has an opening in fluid communication with a first lumen. In another example, with respect to claim 1, *Carner et al.* fails to disclose a guide member that is configured for longitudinal movement through the first lumen and which has a distal extremity configured for entry into a patient's coronary sinus ostium. *Carner et al.* also fails to disclose a stabilizing member as claimed in claim 1. By way of further example, with respect to claim 14, *Carner et al.* fails to disclose a second opening in the distal shaft section of the tubular support member which is in fluid communication with the second lumen. (2)

Figure 6 of *Carner et al.* clearly shows the closed distal tip of the ablation tool described in *Carner et al.* There are no teachings in *Carner et al.* regarding openings in the distal tip of the ablation tool that are in fluid communication with the lumens. Furthermore, there is no teaching or suggestion of a guide member configured to exit the first lumen and enter the coronary sinus ostium.

In addition, *Carner et al.* fails to disclose a stabilizing member. Respectfully, the Examiner erroneously points to element 250 of *Carner et al.* as a stabilizing member. Element 250, as shown in Figures 1 and 6 and described at col. 6, lines 62-63 of *Carner et al.*, is illustrated and described as a pull wire for deflecting the tip of the ablation tool, not as a stabilizing member.

Carner et al. clearly fails to teach several elements of Applicant's claimed subject matter, either expressly or inherently. As such, claims 1-5 and 7-16 are not anticipated by *Carner et al.*

In paragraph 4 on page 4 of the Office Action, claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4033331 to *Guss et al.* and further in view of U.S. Patent No. 4969890 to *Sugita et al.*

To establish *prima facie* obviousness of Applicant's claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

Concerning the third criterion that must be met to support a finding of *prima facie* obviousness of a claimed invention, the combination of *Guss et al.* and *Sugita et al.* fail to teach or suggest all features of Applicant's claim 6. For example, as discussed in more detail above, the asserted combination fails to teach or suggest a guide member or a stabilizing member. Applicant respectfully contends that because the asserted combination fails to teach or suggest all the limitations of Applicant's claim 6, for this reason alone, the Examiner has not met the burden of establishing *prima facie* obviousness of Applicant's invention of claim 6.

The mere fact that *Guss et al.* and *Sugita et al.* recite certain elements with some similarity to those of Applicant's invention of claim 6 does not, in and of itself, render Applicant's claim 6 obvious. Rather, the Examiner has the burden of proving that there

is some suggestion or motivation to modify the reference or to combine reference teachings to make the claimed combination that is found in the prior art, and not based on Applicant's disclosure. This requirement must be met in order to support a finding of *prima facie* obviousness of Applicant's claimed invention.

The actual evidence of a suggestion, teaching or motivation to combine prior art references must be shown, and that this evidence be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). Broad conclusory statements regarding the teaching of references, standing alone, are not evidence. *Id.* Respectfully, the Examiner has provided only a broad, conclusory and unsupported statement regarding motivation using the *Guss et al.* and *Sugita et al.* teachings, which does not meet the burden imposed on the Examiner to make out a *prima facie* case of obviousness.

Because the *Guss et al.* and *Sugita et al.* references in combination fail to teach or suggest several of the above-identified features of claim 6, and because no motivation or suggestion to combine these reference teachings can be identified in the references themselves, and further because the asserted combination does not provide a sufficient basis to support a reasonable expectation of success, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicant's subject matter recited in claim 6.

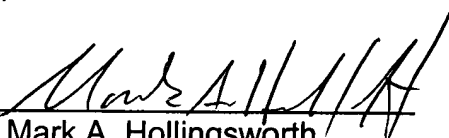
As discussed above, the references cited by the Examiner clearly fail to teach all the features of Applicant's claimed subject matter as claimed in independent claims 1, 14, and 17-19, either expressly or inherently. As such, independent claims 1, 14, and 17-19 are not anticipated by either *Guss et al.* or *Sugita et al.* Because claims 2-13 and 15-16, which depend directly or indirectly on claims 1 or 14, include the features recited in the independent claims as well as additional features, Applicant submits that claims 2-13 and 15-16 are also patentably distinct from *Guss et al.* and *Sugita et al.*

It is believed that claims 1-19 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
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